

Update on Effectiveness and Impact of PCV13 use among U.S. Children

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Context:

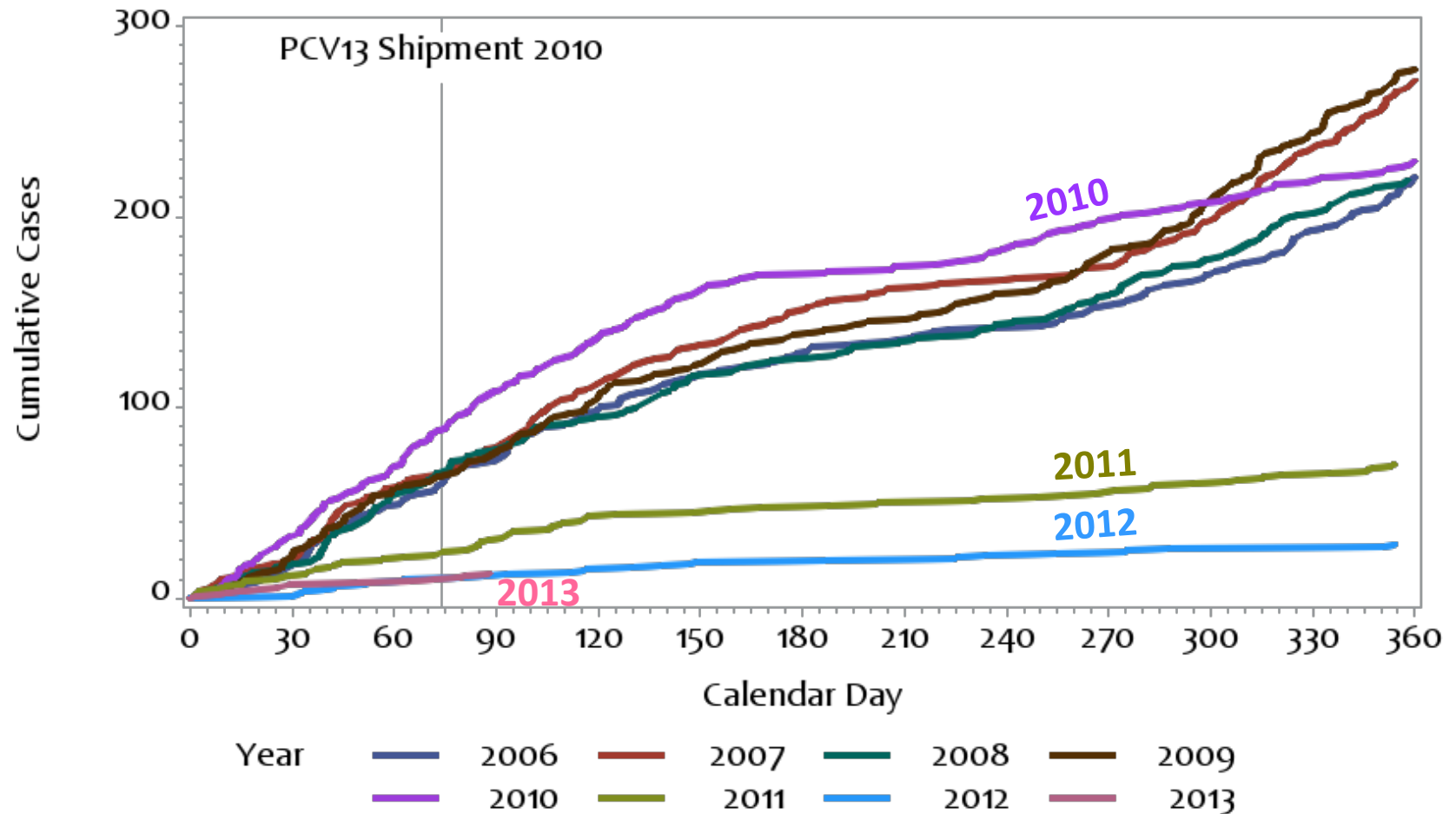
13-valent pneumococcal conjugate vaccine (PCV13)

- FDA Licensure
 - February 2010
 - Based on non-inferior immunogenicity against serotypes common to both PCV13 and PCV7
 - No randomized controlled trial with clinical endpoints
- ACIP Recommendations
 - February 2010 for all infants at 2, 4, 6, 12-15 months
 - Infants who started schedule with PCV7 recommended to finish routine doses with PCV13
 - “Serotype catch-up” for children fully vaccinated with PCV7: a single “supplemental” dose PCV13 for all children <5 years
- Coverage among 19-35 month-olds during 2012*:
 - ≥ 3 doses: 92.3% +/- 0.8%
 - ≥ 4 doses: 81.9% +/- 1.1%

Methods

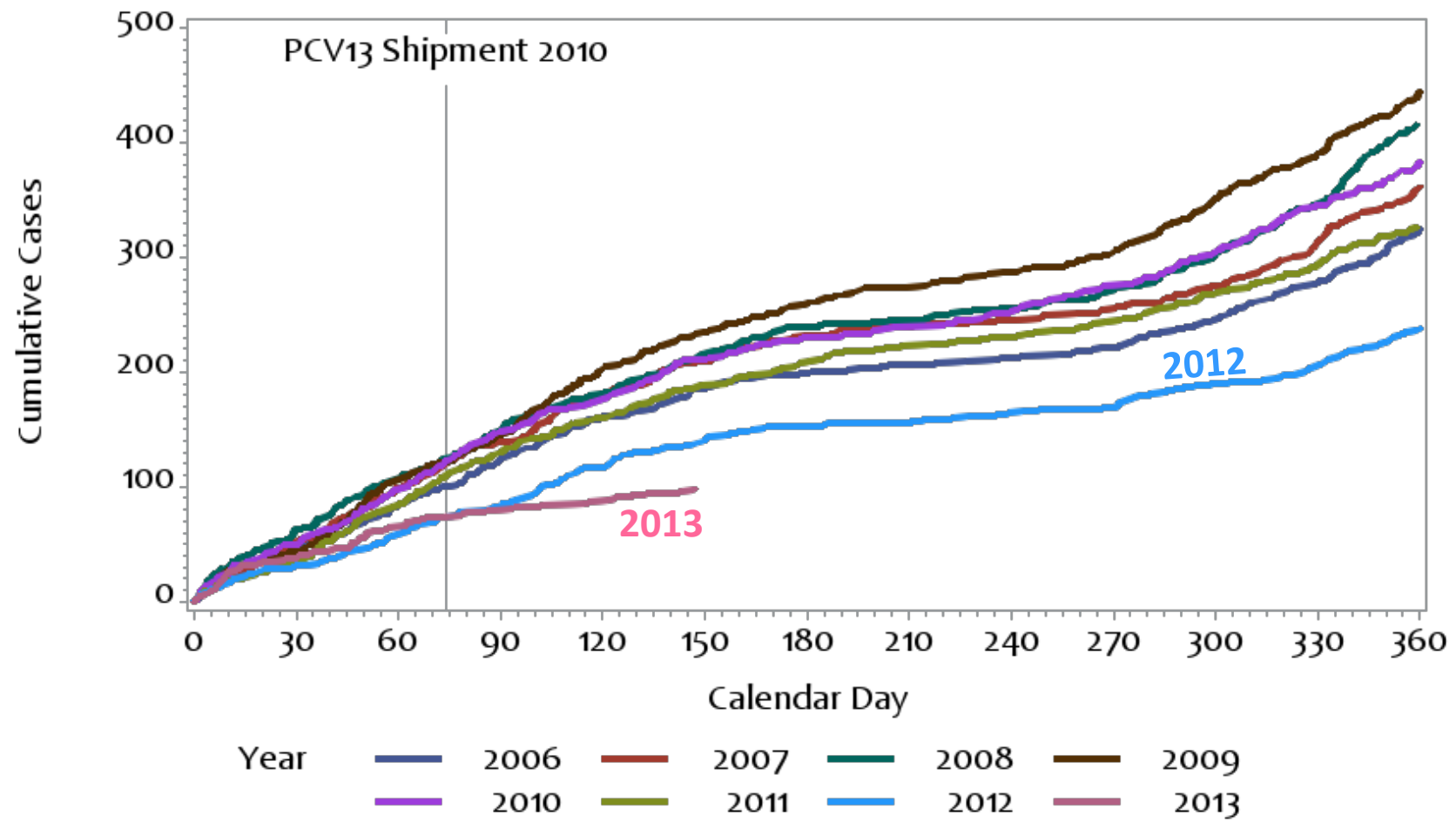
- CDC monitors invasive pneumococcal disease (IPD) using active, population-based surveillance conducted in 10 areas around U.S.
- Evaluated cumulative counts of IPD
- Modeled observed vs. expected counts of IPD
- Case-control study of vaccine effectiveness (VE) among children 2-59 months old

Cumulative Cases of PCV5-type IPD among children <5 years old, 2006-2013



Clear evidence of persistent direct effect....

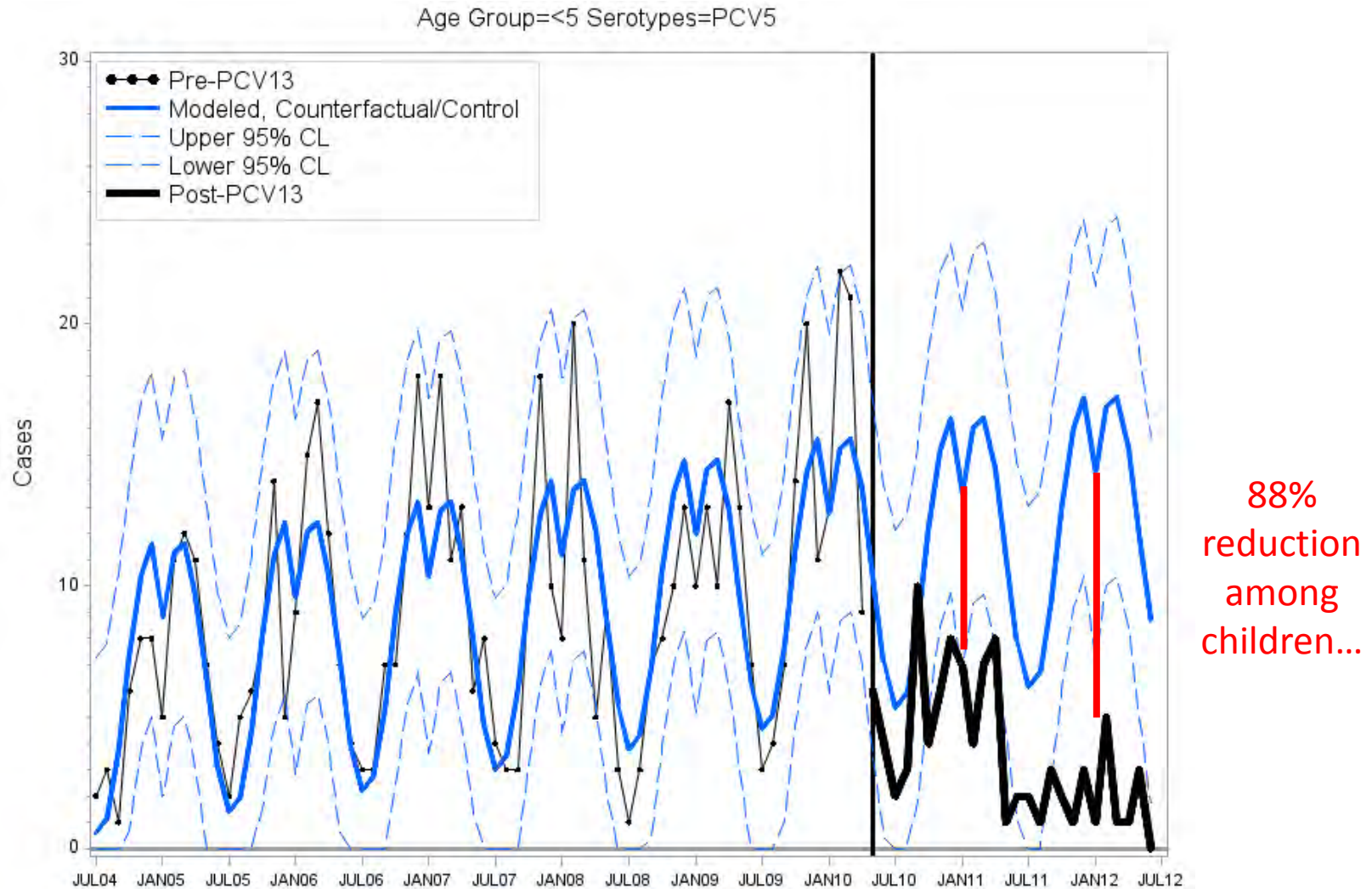
Cumulative Cases of PCV5-type IPD among adults >64 years old, 2006-2013



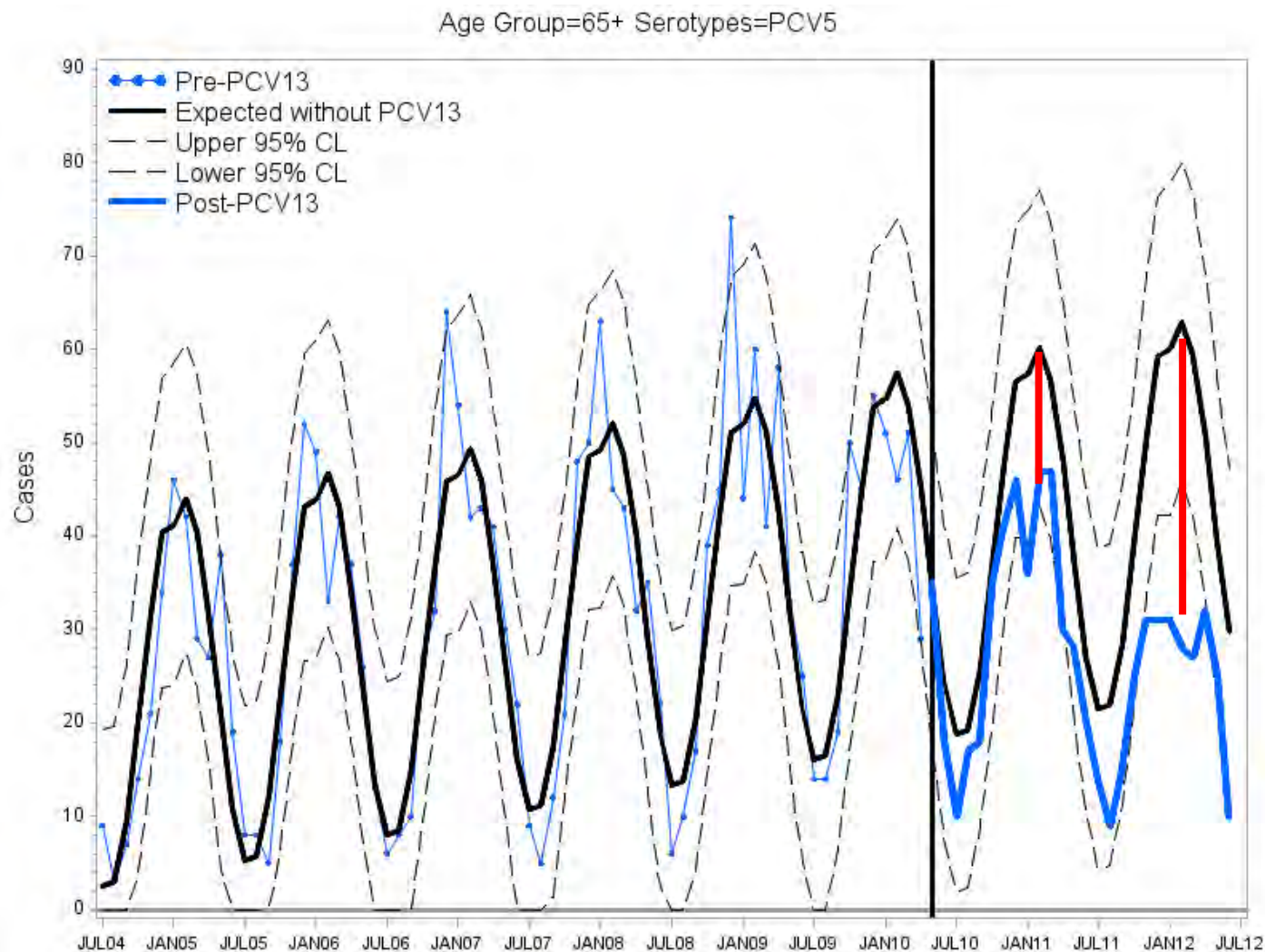
... and indirect effects.

“PCV5” types include those in PCV13 but not in PCV7.

Observed vs. Expected Cases of PCV5-type IPD among Children <5 years old, July 2004-June 2012



Observed vs. Expected cases of PCV5-type IPD among Adults ≥ 65 years old, July 2004-June 2012



...and 47%
reduction
among
adults.

Percent Change in PCV5-type IPD, Comparing Observed Cases to Cases Expected in Absence of PCV13, by age

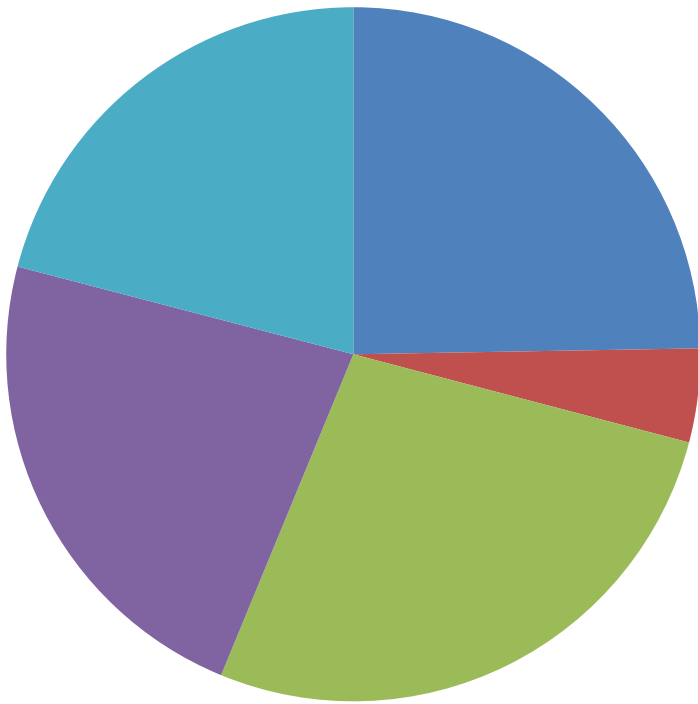
Age group, years	Percent Decrease in Rate (95%IE)	
	2010-11	2011-12
<5	67 (62, 70)	88 (86, 89)
5-17	35 (22, 45)	59 (48, 66)
18-49	33 (26, 38)	65 (60, 68)
50-64	24 (18, 28)	54 (51, 58)
≥65	23 (13, 31)	47 (39, 53)

Statistically significant reductions in vaccine-type IPD in all age groups within first 2 years after PCV13 introduction.

National Cases & Deaths of PCV5-type IPD Prevented following PCV13 Introduction, July 2010-June 12

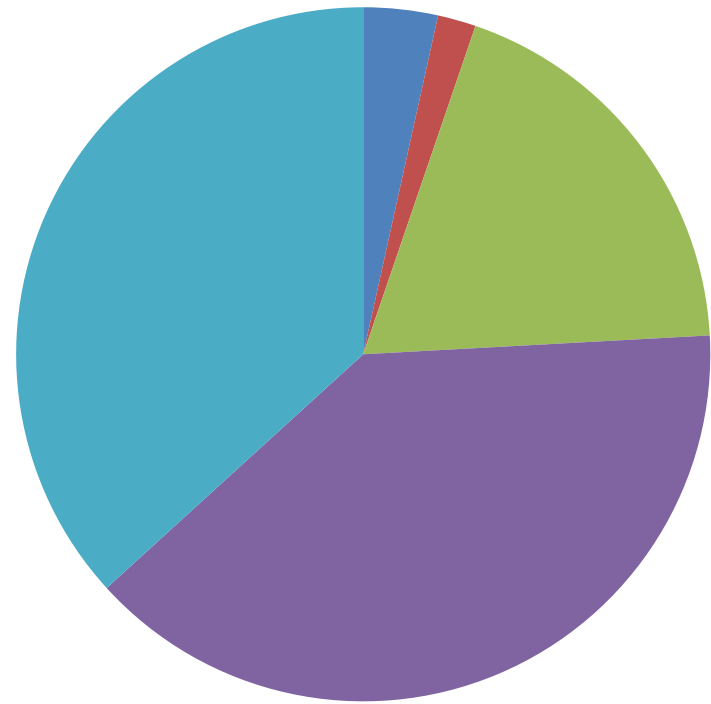
20,000 cases prevented

■ <5 ■ 5 to 17 ■ 18 to 49 ■ 50 to 64 ■ >64



2,000 deaths prevented

■ <5 ■ 5 to 17 ■ 18 to 49 ■ 50 to 64 ■ >64



Case-Control Study of PCV13 Effectiveness: Preliminary Estimates

- Cases: 2-59 month-old children with IPD residing in 10 ABCs areas, New York City, Los Angeles County, Utah
- Controls: 4 per case matched on age (+/- 2wks) & zip code
- May 2010-May 2013
 - Enrolled 765 cases
 - 224 (29%) had PCV13-type IPD
 - 209 (93%) were caused by serotypes 19A, 7F, and 3
 - Enrolled 2274 controls (mean 3 controls per case)
 - Receipt of ≥ 1 dose among controls increased from 37% in June-November 2010 to 96% in December 2012-May 2013

Outcome	VE ≥ 1 dose, %	95% CI
All IPD	65	52-75
PCV13-type IPD	89	79-95
Serotypes 19A, 7F, 3 (as a group)	89	79-95
Serotypes 19A, 7F (as a group)	93	82-97

Summary

- 89% effectiveness of ≥ 1 dose PCV13 vs. PCV13-type IPD
- 88% reduction in PCV5-type IPD among children
- 47% reduction in PCV5-type IPD among adults ≥ 65 years old
- $>20,000$ cases of IPD and $>2,000$ deaths prevented

Conclusions

- PCV13 appears highly effective at preventing IPD among children who receive the vaccine.
- Substantial indirect effects are evident after 3 years of use.

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